

How Pharma Cos. Can Lessen The Risk Of Gov't Action

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The Office of Inspector General for the Department of Health and Human Services publishes semiannual reports to Congress detailing recoveries from actions against pharmaceutical and medical device companies and individuals. [1] These reports detail total monies recovered, which typically are in billions of dollars, and also highlight specific cases and their underlying facts. The cases are instructive to companies looking to avoid being targeted by the government.

For example, a recent report details the outcome of a government action against OtisMed Corp. and its CEO Charlie Chi. The report recites that OtisMed, as a result of pleading guilty to distributing, with intent to defraud and mislead, adulterated medical devices into interstate commerce, agreed to:



Charles Andres

- Pay \$34.4 million in fines and \$5.1 million in forfeiture;
- Pay \$41.2 million to resolve civil False Claims Act liability; and
- Be excluded from participation in Medicare, Medicaid and all other federal health care programs for 20 years (i.e., was barred from vending to the federal government).

Separately, OtisMed's CEO Charlie Chi pled guilty to distributing the medical devices despite the U.S. Food and Drug Administration rejecting the device's premarket clearance application.[2] In June 2015, Chi was sentenced to two years in prison for his actions, ordered to serve one year of supervised release and pay a \$75,000 fine.[3]

The OtisMed case (some would call it an outlier example) highlights the significant consequences that can result from violating broad health care laws. These consequences can include fines, felony convictions, jail time and being barred from vending to the government. Below, we detail actions and statutory violations that can make companies and individuals targets of government action. We also provide recommended practices that can minimize the risk of companies and individuals being targeted by the government.

Off-Label Promotion Under the Federal Food, Drug and Cosmetic Act

For years, the FDA has taken the position that it is a violation of the FDCA for a regulated manufacturer to promote an unapproved or off-label use for an FDA-approved product. Such off-label promotion, the FDA maintains, misbrands[4] the product. According to the FDA, off-label promotion circumvents the

regulatory approval process designed to ensure that medical devices and drugs are safe and effective, thereby endangering the public.

The FDA's position often brings the agency into conflict with the regulated industry that wishes to disseminate and inform prescribing physicians about beneficial off-label uses for their products. Manufacturers have long cited legitimate reasons for disseminating truthful and nonmisleading off-label promotion — for instance, that such promotion helps doctors make informed medical decisions, that these informed decisions directly benefit patients and that off-label use is the standard of care for treating patients in some instances. Manufacturers have also raised the defense that the FDA's prohibition on truthful and nonmisleading off-label promotion violates their First Amendment commercial free speech rights.[5]

Government actions for misbranding and other alleged violations of federal health care laws (e.g., the False Claims Act[6] and the Federal Anti-Kickback Statute[7] (AKS)) continue to occur, even though prosecutions, convictions and significant fines are publicized in the press. Moreover, the penalties for a conviction can be significant. For example, misbranding convictions can result in fines, criminal convictions (including felony convictions) and jail time. Both companies and individuals (e.g., corporate officers) may be tried and convicted for misbranding violations. Whether truthful and nonmisleading off-label promotion constitutes misbranding is therefore an important question with far-reaching consequences.

Recent cases, including the 2015 Amarin[8] district court decision, have made it clear that at least some federal courts side with the regulated industry. For example, the Amarin court held that its "considered and firm view is that ... the FDA may not bring [a misbranding] action based on truthful promotional speech alone, consistent with the First Amendment." [9]

A further important development along these lines recently occurred in the ongoing criminal case involving a medical device manufacturer and its CEO in U.S.A. v. Vascular Solutions Inc. & Howard C. Root.[10] Vascular Solutions and its CEO Howard Root were each charged with four counts of adulteration, four counts of misbranding and felony conspiracy to: introduce adulterated medical devices into interstate commerce, introduce misbranded medical devices into interstate commerce and defraud the United States by concealing the sale of the allegedly adulterated and misbranded medical devices.[11]

In the Vascular Solutions proposed jury instructions, the Department of Justice acknowledged[12] that it "is also not a crime for a device company or its representatives to give doctors wholly truthful and nonmisleading information about the unapproved use of a device." [13]

While this represents a significant step in the evolution of the U.S. government's misbranding jurisprudence, companies and their corporate officers should approach off-label promotion with caution for many reasons:

- First, holdings like Amarin have limited geographic reach. Amarin is a federal district court holding in the Southern District of New York. Should the government bring a misbranding case in a different federal district court, that district court could come to a different conclusion — i.e., that truthful and nonmisleading off-label promotion is not protected by the First Amendment.

- Second, false and misleading off-label promotion is not afforded a First Amendment safe harbor.
- Third, whether off-label promotion is truthful and nonmisleading will be decided on a case-by-case basis by a court that takes into consideration the unique facts of the off-label promotion.
- Fourth, whether something is truthful and nonmisleading can be time dependent. Off-label promotion that is presently truthful and nonmisleading may become false, misleading or both at some future point. For example, a study could publish in a major medical journal that directly refutes the basis for the off-label promotion, potentially rendering the off-label promotion false and misleading as of the date of the study's publication.
- Fifth, it is possible to satisfy one requirement but not the other — e.g., a court could find an off-label promotion to be truthful but also misleading.

Going forward, the FDA may shift its focus toward attempting to prove that off-label promotions are misleading. It may be possible for the FDA to make a misleading allegation stick even when the off-label promotion is truthful. Exemplary situations include:

- Failing to disclose that a publication author has a financial interest in a drug, device or in a publication, when using the publication for off-label promotion;
- Neglecting to inform, during the off-label promotion, of any significant risks or safety concerns known to the company and relating to the unapproved use;
- Failing to provide the approved labeling with the off-label promotion;
- Omitting provision of a comprehensive list discussing contrary authorities to the off-label use; or
- Failing to state, when applicable, that the FDA declined to approve the device for the off-label use.

Companies should take a cautious approach to off-label promotion that minimizes the risk of the FDA and DOJ concluding that the off-label promotion is false, misleading or both. Recommended practices include:

- Comprehensive training of all employees in sales and marketing;
- Implementing standard operating procedures requiring formal review and approval of all promotional materials;
- Establishing a promotional review committee that will be responsible for review and approval of all promotional materials; and
- Strictly adhering to FDA guidance regarding good reprint practices and responses to unsolicited requests for information.

Sunshine Act

The Physician Payments Sunshine Act of 2010 requires applicable drug and medical device manufacturers to report to the government^[14] payments and other "transfers of value"^[15] that are made to physicians^[16] and teaching hospitals. Payments or transfers of value worth at least \$10, and transactions of less than \$10 that in-aggregate total \$100 or more in a calendar year, are generally reportable.^[17] Manufacturers may be fined \$1,000-\$10,000 per unreported payment up to an annual maximum of \$150,000. If the failure to report is deliberate, however, manufacturers can be fined \$10,000-\$100,000 per incident, up to a maximum penalty of \$1 million.

Manufacturers, however, should be aware that complying with Sunshine Act's reporting requirements does not exempt manufacturers from FCA and AKS actions. Because the reported data are publically available,^[18] the data will be used by competitors and the government to build cases of violations under the FCA and AKS. In essence, both the government and competitors will be reviewing the information for potential violations of the law (with competitors looking to forward the information to the government and requesting an investigation).

Federal Anti-Kickback Statute

The AKS^[19] makes it illegal for medical device and pharmaceutical companies to offer or give anything of value in exchange for purchasing any product or service that is reimbursed by the federal government (e.g., Medicare, Medicaid, Tricare). It is also unlawful for physicians, hospitals and health care institutions, to solicit or receive such items of value. The statute is intent-based, requiring that the proscribed actions be knowing and willing.^[20] AKS is a criminal statute and the penalties for violation include felony conviction punishable by imprisonment for up to five years, a fine of up to \$25,000, or both.^{[21],[22]}

Broadly speaking, to minimize the risk of committing AKS criminal violations, manufacturers should think carefully as to whether payments to physicians should be made at all. Before any payments are made, manufacturers should:

- Develop and implement policies and procedures that set forth when a physician can and cannot be engaged to render services, and how to ensure any engagement and payment will comply with the law;
- Systematically document that all payments are for services that are needed and actually used by the company; and
- Support and document that payments represent fair market value.

For medical technology companies, a recommended practice is to adopt and follow the AdvaMed Code of Ethics on Interactions with Health Care Professionals.^[23] Both member and nonmember companies can certify AdvaMed Code adoption. Similarly, it is recommended that pharmaceutical companies adopt and implement the Pharmaceutical Research and Manufacturers of America's Code on Interactions With Health Care Professionals.^[24] The AdvaMed and PhRMA codes specify procedures and organizational structures to be put into place and actions that can and cannot be done when interacting with physicians.

Additionally, some states (e.g., Vermont, California, Massachusetts and Nevada) have compliance laws

regulating the activities of drug and medical device companies. The AdvaMed and PhRMA codes can be helpful in addressing these state law compliance requirements. For example, to fulfill Nevada's requirement that a medical device or pharmaceutical company adopt a marketing code of conduct, Nevada Compliance Program Law has permitted medical device and drug manufacturers to adopt the AdvaMed or PhRMA code without modification.[25]

False Claims Act

The False Claims Act[26] prohibits knowingly making, or causing to be presented, false or fraudulent payment claims to the government. The FCA trebles the government's actual damages, provides for per violation penalties of between \$5,500 and \$11,000, allows for suspension or debarment from vending to the government and permits whistleblower qui tam actions. Individuals and companies can be suspended or debarred. Company debarment can result in bankruptcy and liquidation. Debarring an individual will effectively ensure that the debarred individual will never work for a drug or medical device company that vends to the federal government.

Misbranding can result in FCA violations when drug or medical device claim(s) for an unapproved indication are presented to the government. Thus, having proper procedures and organizational structures in place to minimize the possibility of a misbranding incident can reduce the risk of an FCA violation. Furthermore, companies who elect to disseminate truthful and nonmisleading off-label information about their product should consider, however, that such promotion may nevertheless result in an FCA violation. For example, DOJ has not come out and said that it will not take action if a company disseminates truthful and nonmisleading off-label information.

Conclusion

Drug and medical device manufacturers should act to minimize the risk of violating broad health care laws. Manufacturers intending to promote off-label should take steps to ensure that their promotion is, and remains over time, truthful and nonmisleading. Proactive steps include strictly adhering to FDA guidance regarding good reprint practices and responses to unsolicited requests for information. Manufacturers should be aware that otherwise lawful truthful and nonmisleading off-label promotion could result in FCA violations, and factor this possibility into their decision to disseminate off-label information.

Additionally, manufacturers should note that Sunshine Act data can be used by the government to create a road map for building AKS and FCA cases. Competitors can also mine Sunshine Act data. This data, in conjunction with information developed from the field, by the sales force and physicians who provide data to the competitor, can allow the competitor to anonymously contact the government and request an AKS (or FCA) investigation. Also, large payments or cumulative payments to a physician could trigger concerns from competitors and the government.

Thus, companies should think long and hard as to whether the payments should be made at all. If such payments are deemed desirable, companies should: ensure the payments comply with the law; ensure that the payments are for services that are needed and used; and confirm that payments are for fair market value.

An ounce of prevention now can prevent a pound of government action later.

—By David Hoffmeister, David Van Goor and Charles Andres, Wilson Sonsini Goodrich & Rosati PC

David Hoffmeister is a partner in Wilson Sonsini's Palo Alto, California, office and former senior counsel for drug and device law at Syntex USA Inc. David heads the firm's life sciences/FDA group.

David Van Goor is a patent agent and law clerk in Wilson Sonsini's Washington, D.C., office.

Charles Andres is an associate in Wilson Sonsini's Washington, D.C., office.

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[1] The Fall 2015 OIG Semiannual Report to Congress is available electronically here.

[2] L. Schencker, "Former CEO of Stryker subsidiary sentenced to two years in prison," Modern health care, June 26, 2015.

[3] Id.

[4] 21 U.S.C. § 352. "A device ... shall be deemed to be misbranded ... [i]f its labeling is false or misleading in any particular ... " "Unless its labeling bears (1) *adequate directions for use* ... " (Emphasis added.) Adequate directions for use are determined by the intended use(s) of, e.g., the manufacturer.

21 C.F.R. § 801.4 recites in part that:

The words intended uses ... refer to the objective intent of the persons legally responsible for the labeling of devices ... This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives.

Thus, the FDA reasons that an off-label promotion is an intended use. The intended use, which has not — by definition — been FDA approved, does not have adequate directions for use on the device's label, and the device is therefore misbranded.

[5] The commercial free speech doctrine limits government (e.g., FDA) free speech restriction when the free speech has economic motivation (e.g., to sell a medical device). Under the U.S. Supreme Court's Central Hudson judicial review standard, government restriction of commercial free speech is unconstitutional if the speech discusses a lawful activity and is truthful and nonmisleading unless:

- the government's interest is substantial;
- the regulation directly advances that substantial interest; and
- the regulation is not more extensive than necessary.

Central Hudson Gas and Electric Corp. v. Public Service Commission of New York, 447 U.S. 557, 566 (1980). In practice, the third test prong is most often not met by the government.

[6] 31 U.S.C. §§ 3729-3733.

[7] 42 U.S.C. § 1320a-7(b).

[8] *Amarin Pharma Inc. v. U.S. Food and Drug Administration*, 1:15-cv-03588-PAE (SDNY 2015).

[9] *Id.* at 45.

[10] For a layman's summary of the criminal indictment, see J. Carlson, "Vascular Solutions CEO indicted by Texas grand jury," *StarTribune*, Nov. 13, 2014.

[11] The conspiracy charges are detailed at pages 9-21 and constitute the bulk of the 23-page indictment.

[12] To the authors' knowledge, this is the first time the DOJ has acknowledged that truthful and nonmisleading off-label promotion, on its own, does not constitute misbranding.

[13] Proposed Jury Instructions, *U.S.A. v. Vascular Solutions Inc. & Howard C. Root*, Criminal No. SA:14-CR-926-RCL, filed Jan. 7, 2016.

[14] E.g., to the Department of Health and Human Services.

[15] Payments and transfers of value include but are not limited to cash, cash equivalents, stock, in-kind items, services, consulting fees, compensation for services other than consulting, honoraria, gifts, entertainment, food, travel, ownership or investment interests and royalties or licenses.

[16] Physicians include: MDs, osteopaths, dentists, optometrists, chiropractors and dentists.

[17] States (e.g., Maine, Massachusetts, Minnesota and Vermont) may have additional reporting requirements. Also, at the federal level, the National Institutes of Health and the FDA impose their own separate reporting obligations.

[18] See, e.g., "Open Payments," CMS.

[19] 42 U.S.C. § 1320a-7(b).

[20] Some transactions and arrangements are statutorily exempt from AKS.

[21] In determining whether to pursue an enforcement action, various factors are considered, including: whether remuneration is involved, the potential for adverse consequences to competition by freezing competing suppliers out of the marketplace, the potential for increased charges or reported costs for items or services paid for by Medicaid or Medicare and possible encouragement of overutilization of the Medicare/Medicaid system.

[22] Federal courts and administrative bodies considering the law in the context of actual enforcement cases have established interpretive principles, including but not limited to: i) intent may be inferred from the circumstances of the case; ii) illegal intent and violation of the law may be found even if there is no proof of an actual agreement to order, purchase or recommend the purchase of medical items, services or referrals; iii) the fact that a particular arrangement is common in the health care industry is not a defense to violation of the law; and iv) the law is violated, when a payment has multiple purposes, if even one of the purposes of the payment is: (a) to induce a decision to order, purchase or recommend an item or service; (b) in exchange for ordering, purchasing or recommending an item or service; or (c) is for the referral of patients.

[23] See, e.g., “Code of Ethics,” Advanced Medical Technology Association. The AdvaMed Code can be found [here](#).

[24] See, e.g., “Code on Interactions With Health Care Professionals,” PhRMA. The PhRMA Code can be found [here](#).

[25] AB 128, Statutes of Nevada Chapter 409 (effective Oct. 1, 2007) requires that all wholesalers or manufacturers who employ a person to sell or market a drug, medicine, chemical, device or appliance in Nevada must comply with certain requirements regarding their marketing practices. On Jan. 30, 2008, regulations promulgated by the Nevada State Board of Pharmacy to implement AB 128 became effective. Adoption of the PhRMA or AdvaMed codes without modification can address Nevada compliance requirements.

[26] 31 U.S.C. §§ 3729-3733.

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